

UNITED STATES DISTRICT COURT  
MIDDLE DISTRICT OF FLORIDA AUG -8 PM 2:44  
ORLANDO DIVISION

ARON LEWINGTON and CHRISTINE  
LEWINGTON, his wife,

Plaintiffs,

v.

CASE NO.:

6:14-cv-1283-Orl-18KRS

ENDO PHARMACEUTICALS, INC., a  
foreign corporation, and PROSTRAKAN  
GROUP PLC, a foreign corporation,

Defendants.

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**COMPLAINT AND DEMAND FOR JURY TRIAL**

**COME NOW** the Plaintiffs, Aron Lewington and Christine Lewington, by and through their undersigned counsel, and sue the above-captioned Defendants based upon the predicate facts and causes of action sounding in strict liability, negligence, breach of warranties (implied and express), fraud, negligent misrepresentation, unfair and deceptive trade practices and loss of consortium, as set forth below. Plaintiff, Aron Lewington demands both compensatory (as to all claims) and punitive damages (as to the fraud claims, only), and Plaintiff, Christine Lewington, demands compensatory damages and complain as to the above-captioned Defendants as follows:

**PARTIES, JURISDICTION, AND VENUE**

1. Plaintiffs, Aron Lewington and Christine Lewington ("Plaintiffs") are residents of Cocoa, Brevard County, Florida.

2. Defendant ENDO PHARMACEUTICALS INC. is a Delaware corporation with its principal place of business at 1400 Atwater Drive, Malvern, PA 19355. At all relevant times, ENDO PHARMACEUTICALS INC. researched, developed, marketed, distributed and sold pharmaceutical products including FORTESTA® GEL ("Fortesta"), and was the holder of the exclusive right to commercialize Fortesta in the United States of America.

3. Defendant PROSTRAKAN GROUP PLC. is a United Kingdom company with a place of business and a representative in the United States of America located at 685 Route 202/206, Suite 101, Bridgewater, New Jersey 08807. At all relevant times. Defendant PROSTRAKAN GROUP PLC. was engaged in the research, development, sales, and marketing of pharmaceutical products including Fortesta.

4. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiffs exceeds \$150,000.00, exclusive of interest and costs, and because complete diversity exists between the parties, as Plaintiffs are citizens of Florida, which is different from the states where Defendants are incorporated and have their principal places of business.

5. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. § 1337.

6. Defendants' conduct in designing, licensing, manufacturing, distributing, selling, and marketing the prescription drug Fortesta throughout the

United States, to include, but not to be limited to, the Middle District of Florida, has caused Plaintiff, Aron Lewington, to suffer physical injuries and damages including, but not limited to, ischemic stroke, resulting brain damage and paralysis, pain and suffering, bodily impairment, mental anguish, and diminished enjoyment of life as well as economic loss and other special damages.

7. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because Defendants are subject to personal jurisdiction in accordance with 28 U.S.C. § 1391(c) and because a substantial part of the events giving rise to Plaintiffs claims, to include, but not to be limited to, the sale, purchase and use of Fortesta, occurred within this jurisdiction.

8. On information and belief, at all relevant times, Defendant PROSTRAKAN GROUP PLC. provided and continues to provide Defendant ENDO PHARMACEUTICALS INC. with the exclusive license to commercialize Fortesta in the United States of America, and exclusively supplied and supplies Defendant ENDO PHARMACEUTICALS INC. with Fortesta for the sale in the United States of America.

9. At all times material hereto, Defendant ENDO PHARMACEUTICALS INC. regularly and continually conducted business in the State of Florida and Brevard County. This business included and includes the sale of its product Fortesta in the State of Florida and Brevard County.

10. At all times material hereto, Defendant PROSTRAKAN GROUP PLC. regularly and continually conducted business in the State of Florida and

Brevard County. This business included and includes the sale of its product Fortesta in State of Florida and Brevard County.

FACTS

***Testosterone and Hypogonadism***

11. Testosterone is a primary androgenic hormone responsible for normal growth, development of the male sex organs, and maintenance of secondary sex characteristics.

12. Testosterone plays a role in sperm production, fat distribution, maintenance of muscle strength and mass, and sex drive.

13. Hypogonadism is a specific condition of the sex glands, which in men may involve the diminished production or nonproduction of testosterone.

14. In men, testosterone levels normally begin a gradual decline after the age of thirty.

15. However, this age-related decrease in testosterone levels is not necessarily a sign of any disease and does not rise to the level of diagnosis of hypogonadism in a majority of men.

16. Further, testosterone levels can fluctuate greatly depending on many factors, including sleep, time of day, and medication. Thus, even otherwise healthy men may exhibit low or borderline levels of testosterone depending on circumstances at the time of the test.

***Low Testosterone - a Disease Made Up for Defendants' Profits***

17. Defendants participated in advertising campaigns designed to

convince men that they suffered from low testosterone. Defendants participated in national disease awareness media blitzes that purported to educate male consumers about the signs of low testosterone. The national marketing campaigns consisted of television advertisements, promotional literature placed in healthcare providers' offices and distributed to potential testosterone users, and online media.

18. Defendants' advertisements suggest that various symptoms often associated with other conditions may be caused by low testosterone and encourage men to discuss testosterone replacement therapy with their doctors if they experienced any of the "symptoms" of low testosterone. These "symptoms" include listlessness, increased body fat, and moodiness—all general symptoms that are often a result of aging, weight gain, or lifestyle, rather than low testosterone.

19. Defendants have also sought to convince primary care physicians that low testosterone levels are widely under-diagnosed, and that conditions associated with normal aging could be caused by low testosterone levels.

20. While running these campaigns for the awareness of low testosterone as a disease. Defendants promoted and promote their testosterone products as easy to use topical testosterone replacement therapies.

21. Defendants convinced millions of men to discuss testosterone replacement therapy with their doctors, and consumers and their physicians relied on Defendants' promises of safety and ease. Although prescription

testosterone replacement therapy had been available for years, millions of men who had never been prescribed testosterone flocked to their doctors and pharmacies.

22. However, these men were enticed to take dangerous medication that carries no benefit because many, if not most, of these men did not suffer from any testosterone-related condition that required medical intervention.

23. A study published in the Journal of the American Medical Association ("JAMA") in August 2013 entitled "Trends in Androgen Prescribing in the United States, 2001-2011" indicated that many men who get testosterone prescriptions have no evidence of hypogonadism. For example, one third of men prescribed testosterone had a diagnosis of fatigue, and one quarter of men did not even have their testosterone levels tested before they received a testosterone prescription.

#### ***Defendants' Fortesta***

24. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Fortesta as a testosterone replacement therapy.

25. Fortesta received FDA approval in 2010 for the treatment of adult males who have low or no testosterone. After FDA approval, Defendants widely advertised and marketed Fortesta as safe and effective testosterone replacement therapy.

26. Fortesta is a hydro alcoholic gel containing testosterone. It is

applied to the thighs. The drug enters the body through transdermal absorption.

***The Dangers of Testosterone Therapy***

27. Testosterone therapies, including Fortesta, are not safe drugs, but products which cause life-threatening problems including blood clots, strokes and heart attacks.

28. There have been a number of studies suggesting that testosterone in men increases the risk of serious side effects:

- a. In 2010, a New England Journal of Medicine Study entitled "Adverse Events Associated with Testosterone Administration" was discontinued after an exceedingly high number of men in the testosterone group suffered adverse events.
- b. In November of 2013, a JAMA study entitled "Association of Testosterone Therapy with Mortality, Myocardial Infarction, and Stroke in Men with Low Testosterone Levels" indicated that testosterone therapy raised the risk of death, heart attack and stroke by about 30%.
- c. On January 29, 2014, a study was released in PLOS ONE entitled "Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men." This study indicated that testosterone increases the risk of heart attacks in men over sixty-five years old by 200% and in men younger than sixty-five with a previous diagnosis of heart disease by up to 300%.

29. Secondary exposure to testosterone can cause side effects in others. In 2009, the FDA issued a black box warning for testosterone prescriptions, advising patients of reported virilization in children who were secondarily exposed to the gel. Testosterone may also cause physical changes in women exposed to the drug and cause fetal damage with pregnant women who come into secondary contact with testosterone.

***Defendants Misrepresented and Failed to Warn of the Dangers of Fortesta***

30. Defendants' marketing strategy has been to aggressively market and sell Fortesta by misleading potential users about the prevalence and symptoms of low testosterone. Defendants failed to protect users from serious dangers that Defendants knew, or should have known, can result from the use of Fortesta.

31. Defendants successfully marketed Fortesta by undertaking campaigns designed to create a consumer perception that low testosterone is prevalent among U.S. men and that symptoms previously associated with other physical and mental conditions, such as aging, stress, depression, and lethargy were actually attributable to low testosterone.

32. For example, in connection with the FDA approval of Fortesta, Defendant ENDO PHARMACEUTICALS INC. issued a press release, claiming that "Low T affects nearly 14 million men in the United States, yet only 9 percent (1.3 million) of men diagnosed with Low T are receiving treatment for the condition." Defendants knew, or should have known, these assertions to be

false, and had no reasonable grounds to believe them to be true.

33. Defendants' advertising programs sought to create the image and belief by consumers and their physicians that the use of Fortesta was a safe method of alleviating their symptoms, had few side effects and would not interfere with their daily lives, even though Defendants knew, or should have known, these assertions to be false, and had no reasonable grounds to believe them to be true.

34. Defendants purposefully downplayed, understated and outright ignored the health hazards and risks associated with using Fortesta. Defendants deceived potential Fortesta users by overemphasizing and misrepresenting the prevalence and dangers of low testosterone, while downplaying known adverse and serious health effects of testosterone therapies including Fortesta.

35. Defendants concealed materially relevant information from potential testosterone users and minimized user and prescriber concern regarding the safety of Fortesta.

36. In particular, in the warnings Defendants gave and give in their commercials, online and print advertisements, Defendants had failed and fail to mention significant side effects of Fortesta and had falsely represented and represent that Defendants have adequately tested it for all likely side effects.

37. Defendants did not provide adequate warnings to Plaintiff, Aron Lewington's doctors, Plaintiff, the healthcare community and the general public about the increased risk of serious adverse events that are described herein.

38. The product warnings for Fortesta in effect during the time period

Plaintiff, Aron Lewington used Fortesta were vague, incomplete or otherwise inadequate, both substantively and graphically, to alert prescribing physicians as well as Plaintiff of the serious risks associated with this drug.

39. As a result of Defendants' advertising and marketing, and representations about their products, men in the United States, including Plaintiff, Aron Lewington, pervasively sought out and seek out prescriptions for testosterone including Fortesta.

***Fortesta Caused Plaintiff's Injuries***

40. Plaintiff, Aron Lewington, was prescribed Fortesta and used it from on or about April, 2013 to November of 2013, whereupon, as a direct and proximate result of that prescribed use of Fortesta, he suffered an ischemic stroke, brain damage and paralysis.

41. Within several months of continuous prescribed use of Fortesta, the Plaintiff, Aron Lewington, suffered physical and emotional impairment, which affected his personal and professional life. These impairments include, but are not limited to, suffering an ischemic stroke, brain damage and resulting paralysis.

42. Prior to using Fortesta, Plaintiff, Aron Lewington was in good health had no history of stroke or cardiovascular disease.

43. Plaintiff, Aron Lewington, was approximately 43 years of age when he was prescribed and used Fortesta for symptoms he, and his physician, attributed to low testosterone.

44. In choosing to take Fortesta, Plaintiff, Aron Lewington, and Plaintiff's

physician relied on the marketing and claims made by Defendants that testosterone, therapy, through the use of Fortesta, had been clinically shown to safely and effectively raise testosterone levels and alleviate those symptoms.

45. Had Plaintiff, Aron Lewington, and/or Plaintiff's physician been adequately warned of the potential life-threatening side effects of Fortesta, to include, but not to be limited to ischemic stroke, brain damage and paralysis, Plaintiff, Aron Lewington would not have purchased or taken Fortesta.

46. As a result of using Fortesta, Plaintiff, Aron Lewington, was caused to suffer continuing bodily injury, including, without limitations, ischemic stroke, resulting brain damage and paralysis, and was thus caused to sustain severe and permanent personal injuries, pain, suffering, and mental anguish.

**DISCOVERY RULE & FRAUDULENT CONCEALMENT**

47. Defendants are estopped from asserting a statute of limitations defense because all Defendants fraudulently concealed from Plaintiff, Aron Lewington, the nature of Plaintiff's injury and the connection between the injury and all Defendants' tortious conduct.

**COUNT I: STRICT LIABILITY - FAILURE TO WARN**

48. Plaintiff, Aron Lewington, reasserts, realleges and incorporates by reference the allegations contained within Paragraphs 1 through 47, as if here fully set forth.

49. Fortesta was defective due to inadequate warnings or instruction for use, both prior to marketing and post-marketing. Defendants knew or should

have known that Fortesta created significant risks of serious bodily harm to consumers of the Fortesta product, to include, but not to be limited to, ischemic stroke, brain damage and paralysis. Defendants failed to adequately warn consumers and their healthcare providers of such risks.

50. Because of Defendants' marketing and failure to provide adequate warnings with the product, Fortesta, which the Defendants designed, sold, supplied, marketed or otherwise introduced into the stream of commerce, the Plaintiff, Aron Lewington was prescribed and used Fortesta.

51. Defendants are strictly liable to the Plaintiff, Aron Lewington, for placing the Fortesta product in the stream of commerce with inadequate warnings of the potential, life-threatening side effects and proper instruction for its use.

52. As a direct, proximate and legal cause of the Defendants' failure to warn and the prescribed use of Fortesta, the Plaintiff, Aron Lewington, has suffered serious physical injuries, harm, damages and economic loss. Plaintiff will continue to suffer such harm, damages and economic loss in the future.

53. As a direct and proximate result of the actions of the Defendants, the Plaintiff, Aron Lewington, has suffered and continues to suffer pain, disability, physical impairment, disfigurement, mental anguish, inconvenience and loss of the capacity for the enjoyment of life.

**WHEREFORE**, for the foregoing reasons, Plaintiff, Aron Lewington, respectfully demands judgment against the Defendants and an award of

compensatory damages, in addition to all costs, interest and fees, including attorneys' fees, to which he is entitled under law and such other relief as this Honorable Court deems appropriate, proper and just.

**COUNT II: STRICT LIABILITY - DEFECTIVE DESIGN**

54. Plaintiff, Aron Lewington, reasserts, realleges and incorporates by reference the allegations contained within Paragraphs 1 through 47, as if here fully set forth.

55. Fortesta was in a defective condition and unreasonably dangerous due to inadequate testing, warnings and instructions for use, which created significant health risks and threat of serious bodily harm to consumers at large, including Plaintiff, Aron Lewington.

56. Defendants are strictly liable for Fortesta which was in a defective condition and unreasonably dangerous because of the inadequate and incomplete testing, and warnings and instructions for use to Plaintiff, Aron Lewington, and Plaintiff's physicians.

57. Defendants are strictly liable for Fortesta which was in a defective condition and unreasonably dangerous because of its design.

58. The risk-utility of Fortesta as a treatment for a contrived and pharmaceutical industry-created and -driven condition known as "Low T" was such that this product presented substantial and unreasonable risk with unproven safety or utility.

59. Consumers, including Plaintiff, Aron Lewington, and Plaintiff's

physicians, had the expectation that Fortesta, as designed, tested, and placed within the stream of interstate commerce, was safe and effective for the uses outlined by the Defendants, detailed to physicians, and advertised to the public at large by way of direct-to-consumer advertising.

60. Plaintiff, Aron Lewington, used Fortesta, which the Defendants manufactured, designed, sold, supplied, marketed or otherwise introduced into the stream of commerce, and Fortesta caused serious physical injuries to Plaintiff. Defendants' defective design and testing of Fortesta is the legal cause of Plaintiff's serious physical injuries, harm, damages and economic loss. Plaintiff will continue to suffer such harm, damages and economic loss in the future.

61. As a direct and proximate result of the actions of the Defendants, the Plaintiff, Aron Lewington, has suffered and continues to suffer pain, disability, physical impairment, disfigurement, mental anguish, inconvenience and loss of the capacity for the enjoyment of life.

**WHEREFORE**, for the foregoing reasons, Plaintiff, Aron Lewington, respectfully demands judgment against the Defendants and an award of compensatory damages, in addition to all costs, interest and fees, including attorneys' fees, to which he is entitled under law and such other relief as this Honorable Court deems appropriate, proper and just.

**COUNT III: NEGLIGENCE**

62. Plaintiff, Aron Lewington, reasserts, realleges and incorporates by reference the allegations contained within Paragraphs 1 through 47, as if here

fully set forth.

63. Defendants had a duty to exercise reasonable care in the design, formulation, testing, manufacture, labeling, marketing, sale and/or distribution of Fortesta. In particular, they had a duty to assure that their products did not pose an unreasonable risk of bodily harm and adverse events.

64. Defendants failed to exercise reasonable care in the design, formulation, manufacture, sale, testing, marketing, or distribution of Fortesta in that they knew or should have known that Fortesta could cause significant bodily harm or death and was not safe for use by certain types of consumers.

65. Defendants failed to exercise ordinary care in the labeling of Fortesta and failed to issue to consumers and their healthcare providers adequate warnings concerning the risks of serious bodily injury or death due to the use of Fortesta.

66. Despite the fact that Defendants knew or should have known that Fortesta posed a serious risk of bodily harm to consumers, Defendants unreasonably continued to manufacture and market Fortesta and failed to exercise reasonable care with respect to post-sale warnings and instructions for safe use.

67. At all relevant times, it was foreseeable to Defendants that consumers, like Plaintiff, Aron Lewington, would suffer injury as a result of their failure to exercise ordinary care as described above.

68. As a direct and proximate result of Defendants' negligence, Plaintiff,

Aron Lewington, has suffered physical injuries, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

69. As a direct and proximate result of the negligence of the Defendants, the Plaintiff, Aron Lewington, has suffered and continues to suffer pain, disability, physical impairment, disfigurement, mental anguish, inconvenience and loss of the capacity for the enjoyment of life.

**WHEREFORE**, for the foregoing reasons, Plaintiff, Aron Lewington, respectfully demands judgment against the Defendants and an award of compensatory damages, in addition to all costs, interest and fees, including attorneys' fees, to which he is entitled under law and such other relief as this Honorable Court deems appropriate, proper and just.

**COUNT IV: NEGLIGENT MARKETING**

70. Plaintiff, Aron Lewington, reasserts, realleges and incorporates by reference the allegations contained within Paragraphs 1 through 47, as if here fully set forth.

71. Defendants had a duty to exercise reasonable care in the marketing of Fortesta. In particular, they had a duty to assure that their products did not pose an unreasonable risk of bodily harm and adverse events.

72. Defendants failed to exercise reasonable care in the marketing of Fortesta in that they knew or should have known that this product could cause significant bodily harm or death and was not safe for use by consumers including

Plaintiff, Aron Lewington.

73. Defendants failed to exercise ordinary care in the initial design of Fortesta, in the failure to investigate information about the risks Fortesta poses, and in their decision to continue to sell Fortesta despite those unreasonable risks.

74. At all relevant times, it was foreseeable to Defendants that consumers, like Plaintiff, Aron Lewington, would suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

75. As a direct and proximate result of Defendants' negligence, Plaintiff, Aron Lewington, has suffered physical injuries, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

76. As a direct and proximate result of the negligence of the Defendants, the Plaintiff, Aron Lewington, has suffered and continues to suffer pain, disability, physical impairment, disfigurement, mental anguish, inconvenience and loss of the capacity for the enjoyment of life.

**WHEREFORE**, for the foregoing reasons, Plaintiff, Aron Lewington, respectfully demands judgment against the Defendants and an award of compensatory damages, in addition to all costs, interest and fees, including attorneys' fees, to which he is entitled under law and such other relief as this Honorable Court deems appropriate, proper and just.

COUNT V: NEGLIGENT DESIGN

77. Plaintiff, Aron Lewington, reasserts, realleges and incorporates by reference the allegations contained within Paragraphs 1 through 47, as if here fully set forth.

78. Defendants had a duty to exercise reasonable care in the design of Fortesta. In particular, they had a duty to assure that their products did not pose an unreasonable risk of bodily harm and adverse events.

79. Defendants failed to exercise reasonable care in the design of Fortesta in that they knew or should have known that this product could cause significant bodily harm or death and was not safe for use by consumers, including Plaintiff, Aron Lewington.

80. At all relevant times, it was foreseeable to Defendants that consumers, like Plaintiff, Aron Lewington, would suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

81. As a direct and proximate result of Defendants' negligence, Plaintiff, Aron Lewington, has suffered physical injuries, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

82. As a direct and proximate result of the negligence of the Defendants, the Plaintiff, Aron Lewington, has suffered and continues to suffer pain, disability, physical impairment, disfigurement, mental anguish, inconvenience and loss of the capacity for the enjoyment of life.

**WHEREFORE**, for the foregoing reasons, Plaintiff, Aron Lewington, respectfully demands judgment against the Defendants and an award of compensatory damages, in addition to all costs, interest and fees, including attorneys' fees, to which he is entitled under law and such other relief as this Honorable Court deems appropriate, proper and just.

**COUNT VI: FRAUD**

83. Plaintiff, Aron Lewington, reasserts, realleges and incorporates by reference the allegations contained within Paragraphs 1 through 47, as if here fully set forth.

84. Defendants knowingly and intentionally made materially false and misleading representations to the Plaintiff, Aron Lewington, Plaintiff's healthcare providers and to the public, to the effect that Fortesta was safe for use and that their labeling, marketing and promotional materials fully described all known risks associated with their product.

85. Defendants' representations were in fact false. Fortesta is not safe for use and Defendants' labeling, marketing and promotional materials did not fully describe all known risks of the product, to include, but not to be limited to ischemic stroke, cardiovascular disease, brain damage and paralysis.

86. Defendants had actual knowledge that Fortesta created an unreasonable risk of serious bodily injury and death to consumers, including the risk of the injury that Fortesta caused in Plaintiff, Aron Lewington.

87. Defendants knowingly and intentionally omitted this information from

their labeling, marketing, and promotional materials and instead labeled, promoted and marketed their products as safe for use in order to increase and sustain sales.

88. When Defendants made representations that Fortesta was safe for use, they knowingly and intentionally concealed and withheld from Plaintiff, Aron Lewington, Plaintiff's physicians and the public, the fact that Fortesta was not safe for use, and causes serious side effects, including the injuries that Fortesta caused in Plaintiff, Aron Lewington.

89. Defendants had a duty to fully disclose the risks associated with Fortesta use, including the risk of the injuries that Fortesta caused in Plaintiff, Aron Lewington. Defendants had superior knowledge of these facts that were material to the decisions of Plaintiff, Aron Lewington, and Plaintiff's healthcare providers to use Fortesta.

90. Plaintiff, Aron Lewington, and Plaintiff's healthcare providers reasonably and justifiably relied on the Defendants' representations that Fortesta was safe for use and that Defendants' labeling, marketing and promotional materials fully described all known risks associated with the product.

91. Plaintiffs did not know, and could not have learned of the facts that the Defendants omitted and suppressed. The facts suppressed and concealed by the Defendants are material. Had Plaintiff, Aron Lewington, and Plaintiff's healthcare providers known the truth concerning the risks associated with Fortesta use, Plaintiff, Aron Lewington, would not have used Fortesta.

92. As a direct and proximate result of Defendants' misrepresentations and concealment, Plaintiff, Aron Lewington, was prescribed and used Fortesta, and has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

93. The foregoing acts, conduct and omissions of Defendants were vile, base, willful, malicious, wanton, oppressive and fraudulent, and were done with a conscious disregard for the health, safety and rights of Plaintiff, Aron Lewington, and other users of Defendants' products, and for the primary purpose of increasing Defendants' profits. As such, Plaintiff, Aron Lewington, is entitled to exemplary and punitive damages.

**WHEREFORE**, for the foregoing reasons, Plaintiff, Aron Lewington, demands judgment against the Defendants and an award of punitive and exemplary damages in addition to all costs, interest and fees, including attorneys' fees, to which he is entitled under law and such other relief as this Honorable Court deems appropriate, proper and just.

**COUNT VII: FRAUD - CONCEALMENT,  
SUPPRESSION OR OMISSION OF MATERIAL FACTS**

94. Plaintiff, Aron Lewington, reasserts, realleges and incorporates by reference the allegations contained within Paragraphs 1 through 47, as if here fully set forth.

95. Defendants omitted, suppressed, or concealed material facts concerning the dangers and risks associated with the use of Fortesta, including but not limited to, the risks of the injuries that Fortesta caused in Plaintiff, Aron

Lewington, and the fact that safer alternatives were available. Further, Defendants purposely downplayed and understated the serious nature of the risks associated with use of Fortesta in order to increase and sustain sales.

96. As a direct and proximate result of Defendants' concealment of material facts, Plaintiff, Aron Lewington, was prescribed and used Fortesta and has suffered physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

97. The foregoing acts, conduct and omissions of Defendants were vile, base, willful, malicious, wanton, oppressive and fraudulent, and were done with a conscious disregard for the health, safety and rights of Plaintiff, Aron Lewington, and other users of Defendants' products, and for the primary purpose of increasing Defendants' profits. As such, Plaintiff, Aron Lewington, is entitled to exemplary and punitive damages.

**WHEREFORE**, for the foregoing reasons, Plaintiff, Aron Lewington, demands judgment against the Defendants and an award of punitive and exemplary damages in addition to all costs, interest and fees, including attorneys' fees, to which he is entitled under law and such other relief as this Honorable Court deems appropriate, proper and just.

**COUNT VIII: NEGLIGENT MISREPRESENTATION**

98. Plaintiff, Aron Lewington, reasserts, realleges and incorporates by reference the allegations contained within Paragraphs 1 through 47, as if here fully set forth.

99. Defendants supplied the public and Plaintiffs healthcare providers with materially false and incomplete information with respect to the safety of Fortesta.

100. In supplying this false information. Defendants failed to exercise reasonable care.

101. The false information communicated by Defendants to Plaintiff, Aron Lewington, and Plaintiff's healthcare providers was material, and Plaintiff, Aron Lewington, and Plaintiff's healthcare providers justifiably relied in good faith on the information to Plaintiffs detriment.

102. As a direct and proximate result of Defendants' misrepresentations, Plaintiff, Aron Lewington, was prescribed and used Fortesta and has suffered physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

103. As a direct and proximate result of the negligence of the Defendants, the Plaintiff, Aron Lewington, has suffered and continues to suffer pain, disability, physical impairment, disfigurement, mental anguish, inconvenience and loss of the capacity for the enjoyment of life.

**WHEREFORE**, for the foregoing reasons, Plaintiff, Aron Lewington, respectfully demands judgment against the Defendants and an award of compensatory damages, in addition to all costs, interest and fees, including attorneys' fees, to which he is entitled under law and such other relief as this Honorable Court deems appropriate, proper and just.

**COUNT IX: BREACH OF IMPLIED WARRANTY**

104. Plaintiff, Aron Lewington, reasserts, realleges and incorporates by reference the allegations contained within Paragraphs 1 through 47, as if here fully set forth.

105. Prior to the time that Plaintiff, Aron Lewington, used Fortesta, Defendants impliedly warranted to Plaintiff and Plaintiff's agents and physicians that Fortesta was of merchantable quality and safe and fit for the use for which it was intended.

106. Plaintiff, Aron Lewington, was and is unskilled in the research, design and manufacture of the products such as Fortesta and reasonably relied entirely on the skill, judgment and implied warranty of the Defendants in using Fortesta.

107. Fortesta was neither safe for its intended use nor of merchantable quality, as warranted by Defendants, in that Fortesta has dangerous propensities when used as intended and will cause severe injuries to users.

108. As a result of the abovementioned breach of implied warranties by Defendants, Plaintiff, Aron Lewington, suffered injuries and damages as alleged herein.

**WHEREFORE**, for the foregoing reasons, Plaintiff, Aron Lewington, respectfully demands judgment against the Defendants and an award of compensatory damages, in addition to all costs, interest and fees, including attorneys' fees, to which he is entitled under law and such other relief as this

Honorable Court deems appropriate, proper and just.

**COUNT X: BREACH OF EXPRESS WARRANTY**

109. Plaintiff, Aron Lewington, reasserts, realleges and incorporates by reference the allegations contained within Paragraphs 1 through 47, as if here fully set forth.

110. At all times mentioned, Defendants expressly represented and warranted to Plaintiff, Aron Lewington, and Plaintiff's agents and physicians, by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that Fortesta is safe, effective, fit and proper for its intended use. Plaintiff, Aron Lewington, purchased Fortesta relying on these warranties.

111. In utilizing Fortesta, Plaintiff, Aron Lewington, relied on the skill, judgment, representations, and foregoing express warranties of Defendants. These warranties and representations were false in that Fortesta is unsafe and unfit for its intended uses.

112. As a result of the abovementioned breach of express warranties by Defendants, Plaintiff, Aron Lewington, suffered injuries and damages, as alleged herein.

**WHEREFORE**, for the foregoing reasons, Plaintiff, Aron Lewington, respectfully demands judgment against the Defendants and an award of compensatory damages, in addition to all costs, interest and fees,

including attorneys' fees, to which he is entitled under law and such other relief as this Honorable Court deems appropriate, proper and just.

**COUNT XI: UNFAIR AND DECEPTIVE TRADE PRACTICES**

113. Plaintiff, Aron Lewington, reasserts, realleges and incorporates by reference the allegations contained within Paragraphs 1 through 47, as if here fully set forth.

114. This Complaint is filed and these proceedings are instituted pursuant to applicable consumer protection law including, without limitations, §501.204, *et seq.*, Florida Statutes, to obtain injunctive relief, any other relief this Court deems proper, and attorneys' fees from Defendants.

115. Defendants' acts and business practices constitute unlawful methods of competition and unfair or deceptive acts within the meaning of applicable law including but not limited to the following:

- a. Representing to Plaintiff, Aron Lewington, Plaintiff's physicians and the general public that Fortesta was safe, fit and effective for all patients, knowing that said representations were false;
- b. Concealing from Plaintiff, Aron Lewington, Plaintiff's physicians and the general public that Fortesta had a serious propensity to cause injuries to users;
- c. Engaging in advertising programs designed to create the image, impression and belief by consumers and physicians that the use of Fortesta was safe, and had fewer side effects and adverse reactions than

other options for treating symptoms of low testosterone, even though the Defendants knew these to be false, and/or had no reasonable grounds to believe them to be true;

d. Purposely downplaying and understating the health hazards and risks associated with Fortesta.

116. Defendants' acts and business practices constitute unlawful methods of competition and unfair or deceptive acts within the meaning of applicable law. Plaintiff, Aron Lewington, demands that Defendants immediately cease the illegal conduct alleged herein.

117. The illegal conduct alleged herein is continuing and there is no indication that Defendants will refrain from such activity in the future.

118. Pursuant to §501.211, Florida Statutes, and applicable law, Plaintiff, Aron Lewington, is entitled to declaratory relief, injunctive relief, actual damages, attorneys' fees, and costs.

**WHEREFORE**, for the foregoing reasons, Plaintiff, Aron Lewington, demands judgment against the Defendants and an award of actual damages, declaratory relief, injunctive relief, attorneys' fees and costs and such other relief as this Honorable Court deems appropriate, proper and just.

**COUNT XII: LOSS OF CONSORTIUM**

119. Plaintiff, Christine Lewington, reasserts, realleges and incorporates by reference the allegations contained within Paragraphs 1 through 47, as if here fully set forth.

120. At all times material hereto, Plaintiff, Christine Lewington, was the lawful spouse of Plaintiff, Aron Lewington.

121. As a direct and proximate result of Defendants' conduct, Plaintiff, Christine Lewington, has been deprived of love, society, companionship and services of her husband, Aron Lewington, and has otherwise suffered loss, the extent of which will be more fully adduced at the trial of this matter.

**WHEREFORE**, for the foregoing reasons, Plaintiff, Christine Lewington, respectfully demands judgment against the Defendants and an award of compensatory damages, in addition to all costs, interest and fees, including attorneys' fees, to which she is entitled under law and such other relief as this Honorable Court deems appropriate, proper and just.

**DEMAND FOR JURY TRIAL**

Pursuant to Fed. R. Civ. P. Rule 38(b), the Plaintiffs demand a trial by jury on all issues triable of right by a jury.



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